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By facsimile

16 December 2004

European Patent Office
D-80298 Munchen
Germany

Re: European patent no. 0 676 937B
Corresponding to European patent application no. 94928713.0
Intraluminal Graft
Endogad Research PTY Limited

Dear Sirs

Please find enclosed a notice of opposition to the above-referenced European patent in the name of Endogad Research PTY Limited. The opposition is filed by Scimed Life Sciences, Inc of Maple Grove, Minnesota, USA. The patent is opposed in its entirety and, in the event that the opposition division is inclined to reject the opposition or to maintain the patent in amended form (i.e., any decision other than revocation of the patent in its entirety) the opponent requests oral proceedings under EPCa.116.

Copies of the prior art documents cited in the notice of opposition, which are all readily-available patent documents, will be filed by courier with a confirmatory copy of this fax.

We also enclose a fee voucher form 1010 authorising you to debit our deposit account no. 28050476 in respect of the official opposition fee. If the fee amount stated on the fee voucher is incorrect, then please treat this letter as authority to debit our deposit account in respect of the correct amount such that all necessary official fees are paid before the opposition deadline of 17 December 2004.

It would be appreciated if you would kindly acknowledge safe receipt of this letter and enclosure in the usual way by dating and returning the enclosed form 1037.

Yours faithfully


Julian Richard John Crump
Authorised Representatives

Enc.
Notice of opposition
Fee voucher

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Notice of Opposition to a European Patent

To the
European Patent Office

Tabulation Marks

I. Patent opposed Zur Kasse <i>(A) E 610</i> Patent No. 0 676 937 B Application No. 94928713.0 Date of mention of the grant in the European Patent Bulletin (Art. 97(4), 99(1) EPC) 17-03-2004		for EPO use only Opp. No. OPPO (1)	
Title of the invention: Intraluminal Graft			
II. first named in the patent specification Endogad Research PTY Limited			
Proprietor of the Patent			
Opponent's or representative's references (max. 15 spaces)		28404-902-OPP	
III. Opponent Name Address State of residence or of principle place of business Telephone/Telex/Fax Multiple opponents		OPPO (2)	
Scimed Life Systems, Inc. One Scimed Place Maple Grove Minnesota 55311 USA Minnesota, USA		OREF	
<input type="checkbox"/> further opponents see additional sheet			
IV. Authorisation 1. Representative (Name only one representative to whom notification is to be made) Name Address of place of business Telephone/Telex/Fax Additional representative(s) 2. Employee(s) of the opponent authorised for these opposition proceedings under act. 133(3) EPC Authorisation(s) To 1/2.		OPPO (9) Crump, Julian Richard John Mintz Levin Cohn Ferris and Glovesky Intellectual Property, LLP The Rectory 9 Ironmonger Lane London EC2V 8EY 0044 20 77264000 0044 20 7726 005 <input checked="" type="checkbox"/> (on additional sheet/see authorisation) OPPO (5) Name(s): <input type="checkbox"/> not considered necessary <input type="checkbox"/> has/have been registered under No.	

☐ is/are enclosed
V. Opposition is filed against
☒ — the patent as a whole

☐ — claim(s) No(s).

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VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not patentable (Art. 100(a) EPC) because:

☒ — it is not new (Art. 52(1); 54 EPC)

☒ — it does not involve an inventive step (Art. 52(1); 56 EPC)

☐ — patentability is excluded on other grounds, i.e.
Art. (b) the patent opposed does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC; see Art. 83 EPC). ☐(c) the subject-matter of the patent opposed extends beyond the content of the application/ of the earlier application as filed (Art. 100(c) EPC; see Art. 123(2) EPC). ☐**VII. Facts and arguments**

(Rule 55(c) EPC)

presented in support of the opposition are submitted herewith on a separate sheet (annex 1) ☒**VIII. Other requests:**

The opponent requests oral proceedings.

IX. Evidence presented		for EPO use only
Enclosed = <input checked="" type="checkbox"/> will be filed at a later date = <input type="checkbox"/>		
A. Publications:		Publication date
1 D1 = EP 0 466 518 A2 (Harrison)		
Particular relevance (page, column, line, fig.):		
2 D5 = US-A-5,123,917 (Peter Y. Lee)		
Particular relevance (page, column, line, fig.):		
3 D6 = EP 0 621 016 A1 (C.R. Bard, Inc)		
Particular relevance (page, column, line, fig.):		
4 D7 = US Patent Appln. No. 08/051,728 (Edward I. McNamara)		
Particular relevance (page, column, line, fig.):		
5 D8 = EP 0 646 365 A1 (Parodi, Juan Carlos)		
Particular relevance (page, column, line, fig.):		
6 D9 = EP 0 508 473 A2 (Endovascular Technologies, Inc.)		
Particular relevance (page, column, line, fig.):		
7 D10 = EP 0 539 237 A1 (Cook Incorporated)		
Particular relevance (page, column, line, fig.):		
Continued on additional sheet <input checked="" type="checkbox"/>		
B. Other evidence		
Continued on additional sheet <input type="checkbox"/>		

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Additional sheet

D11 = US-A-4,787,899 (Harrison M Lazarus)

D12 = US-A-5,104,399 (Harrison M Lazaurs)

D13 = US-A-5,163,958 (Leonard Pinchuk)

D14 = WO 83/03752 (Wallsten, Hans)

ANNEX 1 FACTS AND ARGUMENTS

PATENT NUMBER: EP 0 676 937 B

OPPOSITION: Scimed Life Systems, Inc.

DATE: 16 December 2004

REASONED
STATEMENT:

1 Opponent's request

The opponent requests revocation of EP 0 676 937 B in its entirety.

2 Background

EP 0 676 937 B was granted in pursuance of European application no. 94928713.0, based on international application no. PCT/AU1994/000586. PCT/AU1994/000586 was filed on 29 September 1994 with a declaration of priority in respect of earlier Australian application no. PM 153793 dated 30 September 1993.

3 Meaning of certain terms

Claim 1 of EP 0 676 937 B claims:

3.1 "An intraluminal graft comprising a tubular graft body ...".

Claim 1 is silent as to the construction of the graft body. Paragraph [0013] of the patent discloses that the graft body is preferably formed of a thin biocompatible material such as Dacron or PTFE and that the graft may be formed from a material having a limited amount of diametric elasticity. Paragraph [0014] of the patent discloses that the graft body may comprise a body made of woven material or may be non-woven but knitted or of an impervious sheet material.

3.2 "... which is circumferentially reinforced along its length by a plurality of separate, spaced-apart, maleable wires ...".

Claim 1 does not specify that the tubular graft body must be continuously or uniformly reinforced along its length. Further, claim 1, whilst specifying that the wires must be spaced apart, does not specify the maximum spacing between the wires. Accordingly, claim 1 must be construed to encompass

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embodiments in which the tubular graft body is reinforced at a plurality of discrete locations that are longitudinally spaced apart relative to the graft body. Because claim 1 requires the wires to be spaced-apart, the body may be unreinforced at positions intermediate such locations.

3.3 Further, claim 1 does not specify a minimum number of wires that must be provided, other than there must be "a plurality" of such wires, i.e. two or more. Intraluminal grafts are typically cut to size according to the size of the affected area of the vasculature to be treated. This is supported by the disclosure at paragraph [0008] of the patent which discloses that a surgeon may have to shorten a graft. In cases where a short aneurysm is to be treated, the length of the aneurysm may be comparable to the spacing between adjacent wires. In such cases, the graft would comprise only two wires and yet would still meet the requirement of the claim to comprise a plurality of wires.

3.4 "... each of which has a generally closed sinusoidal or zig-zag shape, one of the wires being located adjacent to one end of the graft body such that alternate crests of the wire project longitudinally beyond said end, ...".

Paragraph [0009] of the patent renders the construction of "project longitudinally beyond said end" unclear. For instance, it is apparent that embodiments in which the alternate crests are covered by outer flaps of graft material are regarded to fall within the scope of claim 1; in such cases the apices do not extend beyond the one end of the graft body. See also claim 2. It seems that what is required by this language is that the alternate crests project from and are free from the constraint of the graft body to bell outwardly as described in column 3, lines 1 to 4.

3.5 "...and wherein the wires are interwoven with the graft body."

Paragraph [0014] of EP 0 676 937 B discloses that if the graft body is not woven then the wires may be threaded through suitable holes formed in the graft body. From this it may be clearly inferred that "interwoven" includes embodiments in which the wires pass in and out of - i.e. through - the graft body to interlock the wires and the graft body to prevent separation. (See column 4, lines 1 to 3). It is not a requirement of the claim that the wires be woven into the graft in the strict sense of weaving a fabric. Further, paragraph [0015] specifies that in alternative embodiments the wires may be held in place by sutures or adhesives or may be sandwiched between layers of a multi-layer tubular graft body. Paragraph [0015] states that it is within the ambit of the invention that the wires may be connected to, and be disposed on, the outside surface of the graft body. Clearly a very wide construction of "interwoven" is implied to encompass all these different alternative manners

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of attaching the wires to the graft body.

4 Priority

Claim 1 of EP 0 676 937 B is not entitled to the priority date of 30 September 1993 because it claims an invention that was not disclosed in PM 153793.

4.1 In particular, PM 153793 disclosed an intraluminal graft comprising all the features of claim 1 of EP 0 676 937 B recited above plus the feature that the one wire has "a greater amplitude and smaller wavelength than at least a majority of the other wires in the graft." (See page 3, lines 6 to 8 of PM 153793). This additional feature forms the subject of dependent claim 7 of EP 0 676 937 B. This feature was consistently presented as an essential feature of the invention disclosed by PM 153793; nowhere in the priority application was it disclosed or implied that this feature is optional and may be omitted.

4.2 Accordingly, in line with decisions T 134/94 and T 552/94 the invention disclosed by PM 153793 cannot be regarded as the same invention as the one defined by claim 1 of EP 0 676 937 B as granted. In G 3/93 the Enlarged Board of Appeal found that priority rights cannot be granted if an essential condition - identity of invention - is not fulfilled.

5 Claims 2 to 6 and 8 are also disentitled to the priority date of 30 September 1993 because the subject-matter of those claims was not disclosed by PM 153793.

6 Novelty [EPCa.100(a)]

Claim 1 of EP 0 676 937 B lacks novelty having regard to the disclosures of:

(a) EP 0 621 016 A (D6)

(b) EP 0 646 365 A (D8)

6.1 In particular, D6 was filed on 15 April 1994 with a declaration of priority in respect of earlier US application no. 08/051,728 (D7) dated 22 April 1993. D6 was published on 26 October 1994 after the filing date of EP 0 676 937 B and accordingly forms part of the state of the art in relation to all of the claims of EP 0 676 937 B under EPCa.54(3).

6.2 D6 discloses intraluminal graft (10) comprising a tubular graft body (20). An anchor (30) may be attached to the body (20) adjacent one end thereof, as shown for example in Fig. 13. The anchor (30) comprises a malleable wire having a generally closed zig-zag shape. (See column 6, lines 31 to 32, for example). Fig. 10 shows that alternate crests of the wire project longitudinally

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beyond said end. The wire serves to reinforce circumferentially the graft body, and Figs. 9 to 11 show that the wire is threaded through holes (54) formed in the graft body adjacent the end thereof, such that the wire is interwoven with the graft body in a manner encompassed by claim 1 of EP 0 676 937 B.

6.3 Fig. 13 also shows that such an anchor (30) may be attached to the graft body (20) at each end, such that the body is reinforced at two separate, spaced-apart locations along its length.

6.4 -D6 therefore discloses an intraluminal graft comprising all of the features of claim 1 of EP 0 676 937 B.

6.5 D8 was filed on 26 September 1994 and published on 5 April 1995, after the filing date of EP 0 676 937 B. Accordingly D8 forms part of the state of the art in relation to claims 1, 2 to 6 and 8 of EP 0 676 937 B under EPCa.54(3).

6.6 D8 discloses an intraluminal graft (150) comprising a tubular graft body (160) having first and second ends (161, 162). Sealing means (310) are associated with the second end (162) of the body (160), said sealing means (310) comprising "at least one wire (315)". (See column 17, lines 47 to 49). Column 18, lines 2 to 9 discloses that the wire is woven into the graft body in a generally zig-zag pattern, and column 18, lines 28 to 29 discloses that the wire should be "flexible and malleable". Column 18, lines 45 to 47 discloses that, if desired, more than one wire may be woven into the end (162) of the graft body (160). It is evident from Fig. 18 that where two or more such wires (315) are provided, they are separate and spaced apart, thereby circumferentially reinforcing the graft body (160) at points along its length.

6.7 At column 18, lines 9 to 15, D8 discloses that the wire (315) is woven into the graft body (160) in such a manner that portions (320) of the wire extend outwardly (or inwardly) of the end (162). Column 18, lines 37 to 45 disclose that such portions permit expansion of the end (162) of the body (160). Such portions (320) thus project longitudinally beyond said end in a manner encompassed by claim 1 of EP 0 676 937 B as discussed above.

7 Further, claim 1 of EP 0 676 937 B lacks novelty having regard to:

(a) EP 0 466 518 A2 (D1)

(b) EP 0 508 473 A2 (D9)

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(c) EP 0 539 237 A1 (D10)

7.1 In particular, D1 and D9 each discloses an intraluminal graft (D1: 121; D9: 112) comprising a tubular graft body (122; 112). (See, e.g., Fig. 10 of D1 and Fig. 4 of D9) Opposite ends (123, 124; 113, 118) of the body each carry an expandable spring means (131; 141) comprising a malleable wire formed into a zig-zag shape (Fig. 11; Fig. 8) having alternate crests (133; 132) that project longitudinally beyond said end. Such spring means serve to reinforce the graft body circumferentially at two separate, spaced-apart locations along the length of the body. The spring means are, in each case, attached to their respective ends of the graft body by sutures (146; 144). As discussed above in paragraph 3.5, suturing falls within the definition of "interwoven" provided by EP 0 676 937 B, and accordingly each of D1 and D9 discloses an intraluminal graft having each and every one of the features of claim 1 of EP 0 676 937 B.

7.2 D10 discloses an intraluminal graft comprising a tubular graft body (1). A spring assembly (6) may be attached to the graft body (1) at each end. (See column 7, lines 44 to 48 and Fig. 15). The graft body is thus circumferentially reinforced at two separate, spaced-apart locations along the length of the body (1). Each spring assembly is formed from a length of malleable wire having a zig-zag shape. (Column 7, lines 20 to 23). It is apparent from Fig. 15 that at each end of the graft body (1) alternate crests of the wire project longitudinally beyond said end. Each spring assembly (6) is attached to the graft body (1) by sutures. (Column 7, lines 44 to 48). As stated above, such sutures clearly fall within the definition of "interwoven" provided by EP 0 676 937 B, and accordingly D10 discloses an intraluminal graft having all of the features of claim 1 of EP 0 676 937 B.

8 Inventive step [EPCa.100(a)]

If (which is denied) the Opposition Division should decide, contrary to the above, that the subject-matter of claim 1 is in fact new over the above-mentioned references, then it is observed that such subject-matter lacks an inventive step.

8.1 In particular, if (which is denied) the Opposition Division should decide that suturing wires to a graft body does not produce an "interwoven" arrangement within the meaning of claim 1 of EP 0 676 937 B, then it is observed that the subject-matter of claim 1 lacks an inventive step over the disclosure of D1 in the light of the common general knowledge that can be imputed to the person skilled in the art, because in such case the subject-matter claimed by claim 1 would differ from the intraluminal graft disclosed by D1 only in respect of the manner of attaching the wires to the graft body. D1 discloses suturing the wires (131) to the graft body (122), and the

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opponent observes that interweaving wires with a graft body, or embedding such wires in such a body, would have been obvious, routine alternatives to suturing which were known and available to the skilled person at the filing date of EP 0 676 937 B.

- 8.2 D5 (US 5,123,917), for example, discloses attaching a plurality of separate, spaced-apart malleable wires (30) having a closed zig-zag shape to a graft body (A) by interposing and trapping the wires between two layers (10, 20) of the graft such that the wires are embedded or interwoven in the graft.
- 8.3 D11 (US 4,787,899) discloses a manner of attaching wires (16) to a graft body (12) by threading the wires (16) in and out of the graft body such that the wires are interwoven with the graft body. (See column 4, lines 60 to 64 and Fig. 2).
- 8.4 D12 (US 5,104,399) also discloses a method of attaching a zig-zag shaped wire (16, 17) to a graft body (12) by inserting portions of the wire through the graft such that the wires are interwoven with the graft body. (See Fig. 2).
- 8.5 D13 (US 5,163,958) discloses attaching a graft body (27) to sinusoidal, malleable wire sections (22) by sintering fibres onto the wire sections such that the graft body is wound or braided onto the wires. (See column 4, lines 50 to 55). As shown in Figs. 2 and 3, the end result is that the wire sections (22) and graft body (27) are interwoven.
- 8.6 D14 (WO 83/03752 A1) discloses an intraluminal graft (55) in which wires (2, 3, etc.) are interwoven with an elastic yarn to provide a dense wall. (See page 13, lines 12 to 21 and Fig. 9).
- 9 The subject-matter of EP 0 676 937 B also lacks an inventive step over the disclosures of D9 or D10 in the light of the common general knowledge that can be imputed to the skilled person; the arguments set out above in paragraphs 8.1 to 8.6 apply in respect of each of D9 and D10 severally *mutatis mutandis*.
- 10 The subject-matter of EP 0 676 937 B also lacks an inventive step over the disclosure of D5 in the light of the disclosures of D1 or D9.
 - 10.1 In particular, as acknowledged in paragraph [0004] of EP 0 676 937 B, D5 discloses an intraluminal graft (A) comprising a tubular graft body (10, 20) which is circumferentially reinforced along its length by a plurality of separate, spaced-apart, malleable wires (30), each of which has a generally closed sinusoidal or zig-zag shape. (See Figs. 1 and 5). As discussed above (para. 8.2) the wires (30) are attached to the graft body by interposing and

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trapping them between two layers (10, 20) of the graft, such that the wires are embedded - or interwoven - in the graft.

10.2 D5 differs from the subject-matter of claim 1 of EP 0 676 937 B only in that claim 1 requires one of the wires to be located adjacent to one end of the graft body such that alternate crests of the one wire project longitudinally beyond said end. When the graft is expanded in a vessel by means of a balloon, the crests bell outwardly away from the graft body to engage the vessel wall to assist in resisting any tendency for the graft to move longitudinally within the vessel after insertion. (See para. [0009] of EP 0 676 937 B, lines 34 to 48).

10.3 With reference to D5 as the closest prior art, therefore, the objective problem to be solved is to provide means for resisting any tendency for the graft to move longitudinally within the vessel after insertion. This problem is however solved by D1 (or D9 or D10 *mutatis mutandis*) which discloses the provision at an end of the graft body of an expandable spring means (131) comprising a wire formed into a zig-zag shape (Fig. 11) having alternate crests (133) that project longitudinally beyond said end for ensuring that the graft body does not become dislodged after it has been implanted. (See column 11, lines 22 to 25 for example).

10.4 The person skilled in the art would have been aware of the disclosure of D1 (or D9 or D10 *mutatis mutandis*) and, being faced with the problem outlined above, would have modified the graft of D5 to include an expandable spring means at each end of the graft body, said spring means comprising a wire formed into a zig-zag shape having alternate crests that project longitudinally beyond said end in order to solve that problem.

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